

DETAILED ACTION

Applicants' arguments filed March 15, 2010 have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

However, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Claims 37-50 and 52-72 are pending in this application.

Claims 48-50 and 52 are withdrawn.

Claims 37-47 and 53-72 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 37-47 and 53-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Squires U.S. Patent No. 6,355,684 and Remington's Pharmaceutical Sciences, 1975.

Squires teaches treatment of herpes virus and other infections diseases (see title) such as herpes simplex (instant claim 63)(column 2, lines 25-30) comprising treatment with quaternary ammonium compounds having six to eight carbons (column 3, line 55 to column 4, line 9) such as benzalkonium chloride (see abstract, column 4, line 9, column 5, lines 35-45, column 6, lines 24-41, etc.) along with a solvent (see abstract) such as alcohol (column 4, line 27 and claim 14). The composition is applied by dabbing swabbing, sponging, brushing, or coating infected areas such as oral mucosa (instant claim 69), nasal mucosa, vaginal tissue (instant claim 68), labial tissue, anal tissue, perianal tissue, lips (instant claim 67), cutaneous tissue (instant claim 70), subcutaneous tissue ocular tissue, conjunctiva and eyelids (column 3, lines 29-49). Treatment includes treatment of herpes and other related microbial infections including but not limited to herpes zoster (instant claim 64) (column 2, lines 25-31). The solution is applied in a bottle with an applicator (claims 43-45) (column 4, lines 19-22). It does not teach the size range of the contacting surface relative to the size of the disordered tissue, however, one having ordinary skill in the art could readily determine the size of an applicator required to treat a disorder arising from a virus, bacteria or fungus. Nothing unexpected is demonstrated by the size of the applicator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

employ a towlette or a flat applicator to skin surface since the skin surface is flat thus achieving maximum contact with the skin. Regarding the formation of a reservoir upon application of the composition, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. In this case, Squires teach the same composition (benzalkonium chloride in an aqueous solvent such as alcohol) applied to the same malady (herpes or other infections of the cutaneous tissue or mucous membrane) in the same manner (dabbing swabbing, sponging, brushing, or coating infected areas). It is noted that Squires teaches a composition comprising Echinacea along with benzalkonium chloride, however, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts. Addressing the limitation of instant claims 37 drawn to "the treatment being effective in killing at least of viruses, bacteria or fungus after only a single application of the treatment composition to the disordered tissue", Squires teaches that topically in vivo the herpes simplex infections (a virus) was immediately arrested (column 9, lines 8-10) and when signs of

an outbreak exhibited signaling the prodrome stage of an outbreak, the compound (medicine) was immediately applied by the subject and the outbreak was fully arrested and further symptoms never occurred (column 10, lines 40-46). Squires does not disclose the method wherein the carrier is 20-40% isopropyl alcohol or 70% isopropyl alcohol. Squires however, discloses a concentration of water in an amount of from 15-25% (column 6, lines 36-41) and isopropanol in a concentration of from 20-30% (column 18, lines 5-6) and 10-20% (column 18, lines 40-46). The recitation of the word "about" in instant claims 60-62 causes about 20% to about 40% (claim 60), about 60% to about 80% (claim 61) and about 70% (claim 62) isopropyl alcohol carrier to read on the prior art amount of 10-30% as noted supra. Traditionally, the term "about" permits some tolerance. See, e.g., In re Ayers, 69 USPQ 109 (CCAP 1946), where "at least about 10%" was held to be anticipated by a teaching of a content "not to exceed about 8%." Note, however, that the courts have recently begun to interpret the term far more expansively. See, e.g., Conopco v. May, 24 USPQ2d 1721, 1736 (U.S. District Court, Eastern District of Missouri 1992), where four times was found within scope of "about", where the components of the respective compositions perform substantially the same function in substantially the same manner.

Squires does not disclose the method wherein the composition is no longer visible after about 2 minutes, however, all ingredients are water soluble in an aqueous solvent system. It is not expected that the medicament would be visible. Further, since isopropyl alcohol is a volatile substance, any remaining medicament that is not absorbed would volatilize away, and not be visible. As noted in *In re Best* (195

USPQ 430 (CCPA 1977)), and *In re Fitzgerald*(205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Regarding the limitation of claims 39-42 wherein the method of treatment is by application of the composition by rubbing, rubbing back and forth or compressing the disordered tissue, Remington's Pharmaceutical Sciences, 1975, recites that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph). It would have been made obvious to one of ordinary skill in art at the time it was made to rub or compress the disordered tissue when applying the composition motivated by the teaching of Squires that the composition is topically applied and the teaching of Remington's Pharmaceutical Sciences that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph). Addressing the limitations of instant claims 65 and 66, drawn to the method wherein the disordered tissue comprises at least one lesion caused by smallpox (virus) or anthrax bacteria, Squires teaches the composition to be

effective for other microbial diseases encompassing viruses and bacteria (column 2, lines 46-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a composition of benzalkonium chloride in an aqueous solvent such as isopropanol and water to treat infections such as smallpox virus and anthrax bacteria motivated by the teaching of Squires that other microbial diseases such as bacteria and viruses can be treated with the composition as noted supra.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Response to Arguments

Applicant's arguments with respect to claims 37-47 and 53-72 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Donna Jagoe /D. J./
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March 24, 2010